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Rotational stability of proximally unlocked retrograde femoral nail in damage control surgery – A biomechanical study.

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Abstract

Background: This biomechanical study was performed to look into the rotational stability of retrograde femoral intramedullary nail when it is used without proximal locking as a damage control device for management of femoral shaft fractures in emergency situations. This study compares this technique with the accepted methods for femoral shaft fixations in damage control surgeries. An alternative technique of using lateral compression screw to provide additional rotational stability is described.

Methods: Experiments were divided into four different sets. Distally locked retrograde nail was passed across the fracture without any proximal fixation in set 1, a compression screw passed from lateral cortex in set 2, a proximal locking screw fixation in set 3. In set 4, Saw bone was fixed with an external fixator. The torsion test was applied to create a rotational displacement of 10 degrees and the maximum load required to create the rotational displacement was noted.

Results: Application of a compression screw improved the rotational stability significantly in comparison to no proximal locking. It was observed that there is no statistically significant difference between the lateral compression bolt construct and the external fixation construct in terms of rotational stability.

Conclusions: This study shows that the addition of a lateral compression screw significantly improves the rotational stability and has the potential to be used in emergency lifesaving procedures.

Keywords: Damage control; Femoral shaft fracture; External fixation; Intramedullary nailing; Biomechanical testing.

Introduction

Proximally and distally locked intramedullary nailing (IMN) of femoral shaft fractures is accepted as the standard treatment as part of total early care (TEC) in the hemodynamically stable patient. Unfortunately, in hemodynamically unstable patients, this technique has been associated with greater morbidity and mortality [1,2,3]. Hence calls for less aggressive fixation methods were made. Currently, the use of external fixators as temporary fixation of these fractures as part of damage control orthopaedics (DCO) in these patients is accepted as the treatment of choice [2,4,5].

However, external fixation (EF) in these patients is far from ideal. It affords only partial fracture stability especially in the obese thigh. Pin site infection is another major drawback that has significant bearing on future management options. Knee stiffness because of soft tissue splinting is a third problem. Nursing in intensive care units (ICU), especially if they have bilateral EF, is a major problem in these patients who require regular turning and physiotherapy. Other complications include continued bleeding from the fracture site and rare vascular injuries. Finally, conversion to standard locked IMN nail is a major procedure that may be associated with further complications and additional costs [6,7,8,9]. Recent studies have suggested the use of retrograde intramedullary femoral nail (RIMFN) as an alternative to EF as damage control device [10,11]. The nail is passed gently without reaming and is only locked distally. Proximal locking is done at later stage once the patient's condition has stabilized. This technique has been found to be relatively safe, easy and quick. There is no need for a second major surgical procedure thereby minimizing the chance of the second hit associated with later intramedullary nailing.

However, there are concerns with regards to the rotational stability of the fracture fixation where RIMFN has been used without proximal locking. One option is adding a lateral compression screw proximally, to improve the rotational stability of the construct. To the authors knowledge there are no studies of the biomechanical performance of RIMFN of shaft fractures without proximal locking in terms of rotational stability.

The current experimental investigation was performed to evaluate the role of a proximal lateral compression screw in rotational stability compared to no proximal fixation and standard proximally locked nail. The rotational stability of nail was also compared with External fixation for this injury.

Material and methods

Twelve fourth generation Sawbones (made of fiber filled epoxy cortical shell and cancellous polyurethane core to mimic young healthy femurs) measuring 455mm in length and reamed to an internal diameter of 13 mm (Sawbones Worldwide / Pacific Research Laboratories, Malmö, Sweden) were used.

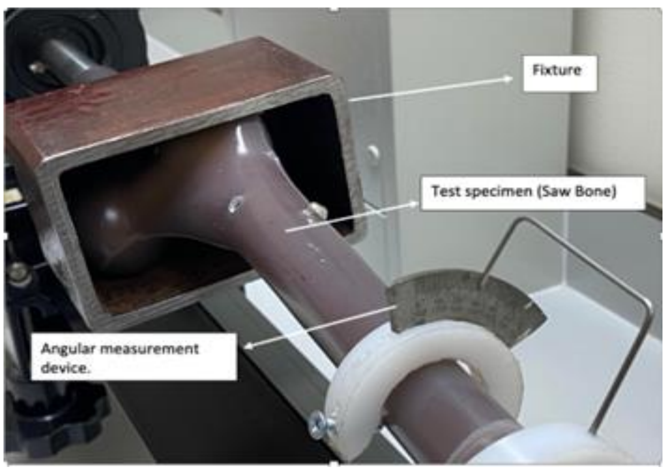
M/DN Femoral Retrograde Intramedullary nails (Zimmer-Biomet, Warsaw, Indiana, USA) length 380mm, and diameter 10mm, proximal screw size 4.2mm, distal screw size 5.5mm were used.

The nail was inserted through the intercondylar notch using the manufacturer's recommended surgical technique. The nail-head was countersunk 2.0 mm relative to the base of the intercondylar notch. Two distal locking screws were inserted using the nail-mounted drill guide. A transverse osteotomy was performed 18cm above the articular surface ensuring free movement of the proximal fragment in relation the distal fragment-nail composite.

The unilateral uniplanar fixator (Sharma Ortho System Pvt Limited, India) was used. Two 6 mm Schanz's pins were inserted bi-cortically in each of the proximal and distal fragments. The core drill-holes were 4.5 mm. The pins were connected using a single rod of 11 mm diameter using rod to pin clamps.

The femur was potted in a mounting fixture containing two customized iron boxes fixing the nail on either end and placed on a servo-hydraulic testing machine (SM1 Mk II Torsion Testing Machine) for mechanical testing (Fig 1).

Fig. 1. Experimental set up demonstrating customized mounting fixture for the nail ends.



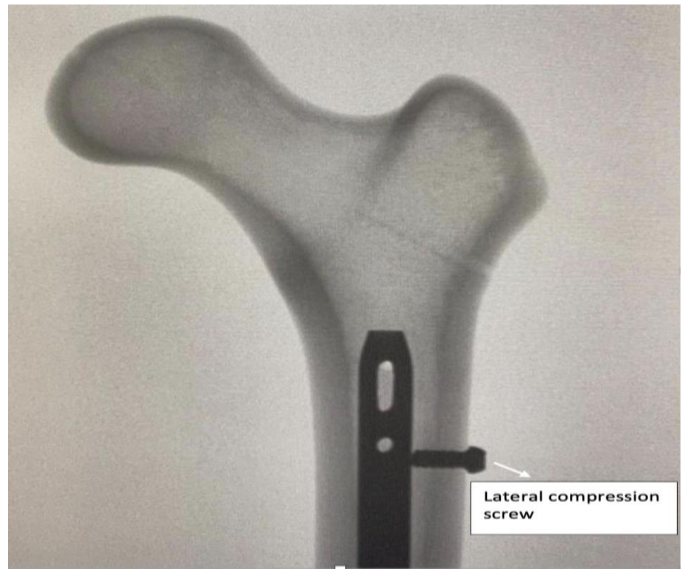
The torsion test was applied to create an angular displacement of 10 degrees and the maximum load required to create the rotational displacement was noted. No load was exerted axially along the femur during torsion testing, thus avoiding frictional resistance at the fracture site. The load/Torque applied was measured in Newton meters (Nm) using digital torque measuring machine (TeCQuipment E -101 Digital Measuring System)

Experiments were divided into four different sets of three saw bones each.

Group 1: Distally locked RIMFN passed across the fracture without any proximal fixation.

Group 2: Distally locked RIMFN passed across the fracture with a 4.2mm blocking bolt (lateral compression screw) was passed through the lateral cortex to compress the nail against the medial cortex (Fig.2).

Fig. 2. Image intensifier X-ray of the lateral compression screw application.



Group 3: Distally locked RIMFN passed across the fracture with one 4.2mm anterior to posterior proximal locking screw.

Group 4: Saw bone was fixed with external fixators, using two Schanz's screws in each fragment.

Each set included three saw bones and for each mode of fixation the biomechanical testing was performed three times.

Statistical analysis using independent paired T test with significance level of $P < 0.05$ was performed.

Results

Table 1 shows the results of each individual reading. The mean torsional loads required to create 10 degrees of rotational deformity in set 1,2,3 and 4 was 0.19, 1.03, 1.44 and 0.83, respectively.

Table 1 Results of biomechanical tests (torque in N.m)

	Nail (NPL)	Nail (B)	Nail (PL)	Ex Fix
Saw bone 1	0.21	0.58	1.66	0.95
	0.20	0.86	1.53	0.92
	0.18	0.96	1.60	0.95
Saw bone 2	0.17	0.74	1.86	0.93
	0.20	0.95	1.50	0.85
	0.17	0.90	1.59	0.85
Saw bone 3	0.21	1.50	1.08	0.74
	0.20	1.41	1.09	0.71
	0.19	1.43	1.09	0.60
Mean	0.1922	1.037	1.4444	0.8333

Nail (NPL): Nail with no proximal locking

Nail (B): Nail with bolt (lateral compression screw)

Nail (PL): Nail with proximal locking

Ex Fix: External fixator

N.m: Newton meters

The standard deviation and standard error for each group are shown in table 2.

Table 2 Mean Torque required to create 10 degrees of rotational displacement for each group.

	N	Mean (Torque N.m)	Std. Deviation	Std. Error Mean
Nail (NPL)	9	0.1922	0.01563	0.00521
Nail(B)	9	1.037	0.3295	0.1098
Nail (PL)	9	1.4444	0.2870	0.0957
Ex Fix	9	0.8333	0.1240	0.0413

Nail (NPL): Nail with no proximal locking

Nail (B): Nail with bolt (lateral compression screw)

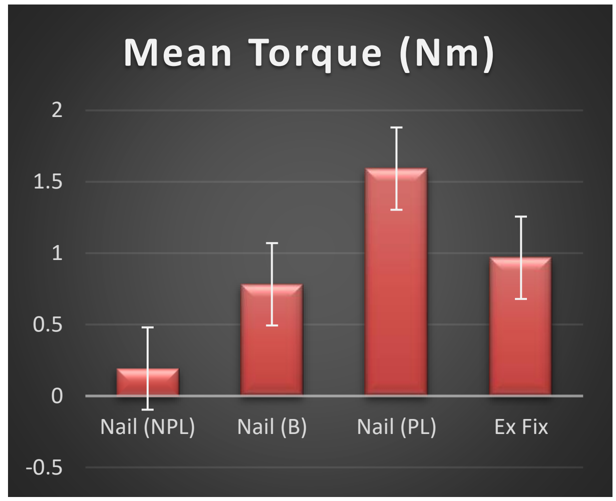
Nail (PL): Nail with proximal locking

Ex Fix: External fixator

N.m: Newton meters

Torsional stability varied between the different groups. As expected, the nail without any proximal screws was the least stable while the nail with proximal locking screw was most stable construct with the other two groups showing intermediate stability (Fig. 3).

Fig. 3: Values of mean torques obtained for different cases.



Nail (NPL): Nail with no proximal locking

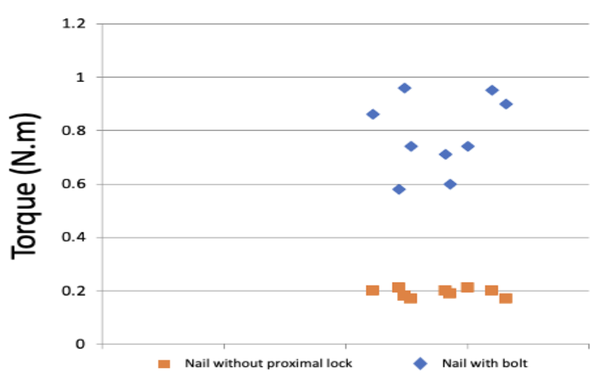
Nail (B): Nail with bolt (lateral compression screw)

Nail (PL): Nail with proximal locking

Ex Fix: External fixator

Application of lateral compression bolt improved the rotational stability significantly in comparison to no proximal locking (Fig. 4).

Figure 4: Scatter diagram depicting the torque loads for Nail with no proximal lock and Nail with bolt (lateral compression screw).



N.m: Newton meters

It was also observed that there is no statistically significant difference between the lateral compression bolt construct and the external fixation construct in terms of rotational stability.

Discussion

This study employed mechanical testing to evaluate the rotational stability of various constructs used in the treatment of femoral fractures in polytrauma scenarios. The results showed that rotational stability was best achieved using a distally and proximally locked retrograde femoral nail. However, this construct is contraindicated in the unstable polytrauma patient where speed and minimal surgical trauma are of vital importance. In these patients, the current standard of care is application of EF with 2 screws in each fragment [4,5]. This construct showed statistically significant lower rotational stability in comparison with the fully locked nail [Mean difference 0.61; 95%CI of difference = 0.39-0.83; p= 0.00].

Traditionally external fixators have been used as damage control devices in polytrauma patients for femoral fixations. Recent published studies have demonstrated the use of retrograde nail for damage control surgery to be efficient, effective, and safe [10,11]. However, passing a nail without proximal locking makes it rotationally unstable which has been a concern against the use of RIMFN as damage control device.

In order to improve the rotational stability, the authors propose the use of screw passed from lateral cortex proximally as a bolt. The screw pushes the nail against the far cortex and minimizes rotation of the nail in the medullary canal. This technique significantly improves the rotational strength in comparison to no proximal fixation (Fig 4). Although, the mean force required to create the rotational displacement was lower in external fixators in comparison to this technique, this difference was not statistically significant (Table 3).

Table 3 Comparative analysis of all groups

S. No	M	CI	Sig (2- tailed)
Pair 1	0.8444	0.6113 to 1.0775	0.00
Pair 2	0.2033	-0.454 to 0.4521	0.102
Pair 3	0.6411	0.5528 to 0.7294	0.00
Pair 4	0.6111	0.3902 to 0.8320	0.00
Pair 5	0.4078	0.0990 to 0.7166	0.01

Pair 1: Nail with lateral compression screw vs Nail without proximal screw

Pair 2: Nail with lateral compression screw vs External Fixator

Pair 3: External fixator vs Nail without proximal screw

Pair 4: Proximal locking screw vs External fixator

Pair 5: Nail with lateral compression screw vs Proximal locking screw

M: Difference of means

CI: 95% Confidence Interval of difference in means

This biomechanical study has shown that using a proximal lateral compression screw provides significant rotational stability and is a quick and simple procedure and requires only a single C arm exposure to identify the proximal end of the nail thereby decreasing the surgical time and at the same time provide significantly improved stability.

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